

## PATENT COOPERATION TREATY

PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 04 JUN 2004

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Rec'd PCT/PTO 08 SEP 2004

Applicant's or agent's file reference P3504A	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA416)	
International application No. PCT/B 03/01403	International filing date (day/month/year) 10.03.2003	Priority date (day/month/year) 08.03.2002
International Patent Classification (IPC) or both national classification and IPC A61M16/00, A61M16/00		
Applicant KAERYS S.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
- ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of 7 sheets.

3. This report contains indications relating to the following items:
- I ☒ Basis of the opinion
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application

Date of submission of the demand  06.10.2003	Date of completion of this report  03.06.2004
Name and mailing address of the International preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Valfort, C  Telephone No. +49 89 2399-2352  

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/IB 03/01403**

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-13 as originally filed

**Claims, Numbers**

1-20 filed with telefax on 27.04.2004

**Drawings, Sheets**

1/7-7/7 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	1-20
	No: Claims	
Inventive step (IS)	Yes: Claims	1,2,4-20
	No: Claims	3
Industrial applicability (IA)	Yes: Claims	1-20
	No: Claims	

2. Citations and explanations

**see separate sheet**

D1: EP-A-1177810  
D2: EP-A-1166813  
D3: EP-A-0821976  
D4: WO-A-9857691  
D5: WO-A-9211054  
D6: WO-A-02053217

**Re Item V**

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. D1 which is considered as the closest prior art discloses an apparatus to assist patient ventilation (see fig.2), from which the subject-matter of claim 3 differs in that the second pressure sensor used to determine the flow at the patient mask is not placed at the output of the blower, but as explained paragraph 44 and 45 of D1 on each sides of an organe which is provided in order to create a pressure drop measured by the two pressure sensors and in that in D1 no mention is made that the control unit comprises offset compensation means for compensating the possible difference of gauging between the two pressure sensors. Nevertheless, in D1 the type of the said organe for providing the pressure drop is not explicitly mentioned, it is clear for the skilled person that said can be a diaphragm, a venturi or any other suitable part creating a known pressure drop. The flow being then derivable from the two pressure values and the Bernouilli law. Moreover it is well known from the skilled person that when two pressure sensors are used in such a measuring system, there is a need to calibrate the two sensors in order to insure proper calculation, a traditional way of doing it is to use offset compensation means. Therefore, the subject-matter of claim 3 does not appear to imply an inventive step (Article 33(3) PCT) in view of document D1 taken with the general knowledge of a skilled person working in fluid mechanics.
2. The subject-matter of claim 1 differs from the device of D1 in that the second pressure sensor is placed at the output of the blower and in that the control unit is devised to calculate the airflow resistance  $K_t$  from a tube to be connected to the apparatus from the pressures measured at the extremity of the tube and at the output of the blower and the coefficient  $K_s$  (airflow resistance known) of a shell with a traversing hole to be connected at the extremity of the tube, and the control unit is able to calculate the airflow through the tube.

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3. The problem to be solved by the invention can therefore be regarded as how to provide an alternative to the flowmeter system of D1.
4. The available documents do not hint at the control unit according to claim 1. D2 which discloses another calibration technique which needs both a flow and pressure sensor leads away from the control unit according to claim 1. (Nevertheless, D6, see point 3. may be of relevance at a latter stage).
5. Claims 2,4-18 (when dependent on claim 4 but not 3), are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.
6. The closest prior art concerning process claims 19 and 20, appears to be document D2, which teaches a breath-hold technique, needing a pressure and flow sensor in order to calibrate and compensate for the breathing tube resistance, using a pressure drop over the time of the breath-hold. Said document appears to lead rather away from the technique used in claims 19 and 20, with the shell having a calibrated hole. Therefore, the subject-matter of claims 19 and 20 appears to imply an inventive step (Article 33(3) PCT).
7. Certain published documents (Rule 70.10)

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO02053217	11/07/2002	24/12/2001	29/12/2000

The document above may be of relevance later in the procedure (see citations in the international search report).